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| 10/580,023          | 03/27/2007  | Gauthier Pouliquen   | 022290.0159PTUS           | 7549             |
| 32042               | 7590        | 05/25/2010           | EXAMINER                  |                  |
| PATTON BOGGS LLP    |             |                      | GUDIBANDE, SATYANARAYAN R |                  |
| 8484 WESTPARK DRIVE |             |                      |                           |                  |
| SUITE 900           |             |                      | ART UNIT                  | PAPER NUMBER     |
| MCLEAN, VA 22102    |             |                      | 1654                      |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                               |                     |  |
|------------------------------|-------------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b>        | <b>Applicant(s)</b> |  |
|                              | 10/580,023                    | POULIQUEN ET AL.    |  |
|                              | <b>Examiner</b>               | <b>Art Unit</b>     |  |
|                              | SATYANARAYANA R.<br>GUDIBANDE | 1654                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 March 2010.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 8,27 and 30-34 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7, 9-26, 28 and 29 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/21/06,2/21/08,6/3/08,9/25/09,3/24/10</u> .                  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of group I (claims 1-26, 28 and 29), election of IFN as the active principle (AP), alpha-L-polyglutamate as biodegradable polymer (PO), alpha-tocopherol as the hydrophobic group (HG) in the reply filed on 8/19/09 and election of formula I with R<sup>1</sup> = H, R<sup>2</sup> = H, R<sup>3</sup> = amine cation, R<sup>4</sup> = a direct bond and A = -CH<sub>2</sub>-CH<sub>2</sub>- in the reply filed on 3/24/10 is acknowledged.

The traversal is on the ground(s) that applicants argue that the independent claims of the instant application are patentable over Hullie (US 6,630,171) citation used in the lack of unity established in the election/restriction mailed on 7/21/09. Applicants further argue that, “[A] finding of Anticipation by a reference requires that the reference teach all limitations of the anticipated claims. Huille et al. fails to meet this requirement at least because it fails to teach liquid formulations are liquid under injection conditions in the presence of a physiological electrolyte and/or a surfactant, yet form a gelled deposit in vivo, which is a feature that is shared by all claims. Accordingly, all of the claims do share a special technical feature and thus do possess unity of invention”. This is not found persuasive because it should be noted that the argument for showing lack of unity was based on the process of preparing delivery particles comprising active principles for administration to an animal via oral, nasal, ocular, intramuscular, intradermal, etc. This technical feature of Hullie reads on the technical feature of the group II invention of the instant application and hence it is not a special technical feature and is not a contribution over the prior art. Hence, the requirement is still deemed proper and is therefore made FINAL.

***Status of the pending claims***

Applicant's amendment to claims in the response filed on 3/24/10 has been acknowledged.

Claims 1-34 are pending.

Claims 27 and 30-34 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 8/19/09.

Claim 8 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/19/09.

Claims 1-7, 9-26, 28 and 29 are examined on the merit.

***Priority***

Applicant's claim for the benefit of a prior-filed foreign application under 35 U.S.C. 119(a-d) is acknowledged, i.e., foreign priority document has been placed in the application file. However, applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a-d) as follows:

The foreign priority document submitted is not in English language. A translation of the same is required to grant the priority. The filing date of the priority document is not perfected unless applicant has filed a certified priority document in the application (and an English language translation, if the document is not in English) (see 37 CFR 1.55(a)(3)). Hence, Huille

(US 6,630,171) is available as a 102(b) reference in the instant case and Chan (US 2006/0099264 A1) is available as a 102(a) reference.

***Claim Objections***

1. Claims 6 is objected to because of the following informalities: a comma (,) is missing after the recitation of ‘aspartic units’ on line 2. Also instead of referring glutamic and aspartic as ‘units’, it would be better if they are referred as ‘glutamic acid and aspartic acid residues’ Appropriate correction is required.
  
2. Claims 7 is objected to because of the following informalities: claim recites the limitation -CH<sub>2</sub>--(a double hyphen). It should be -CH<sub>2</sub>- Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 9-26, 28 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 as presented recite a limitation “wherein said formulation is at least partly caused by at least one physiological protein present in vivo”. It is unclear whether the instant formulation is formulation comprising a physiological protein present in the formulation or the formulation is partly formed in *in vivo*.

The instant claim 1 also recites “and is liquid at the physiological temperature and at the physiological pH and in the presence of: a physiological electrolyte in a physiological concentration, and at least one surfactant”. It is unclear whether the aforementioned limitation is a part of the composition or a property of the composition *in vivo*.

Claim 2 recite that the concentration of PO is set at a value that allows the formation of gelled deposit *in vivo* after parenteral injection, in the presence of at least one physiological protein. The instant invention is drawn to a pharmaceutical composition, however, the claim 2 as presented imply that the completion of the formulation occur after parenteral injection into a patient in the presence of a physiological protein. It is unclear from the claim as presented what is this critical concentration of PO that would allow the composition form a gelled deposit in the presence of which physiological protein after parenteral injection.

Claim 7, recites a limitation that “ $n/(n+m)$  is defined as the molar grafting rate and its value is **sufficiently** low for [PO], dissolved in water at pH 7 and at 25~, to form a colloidal suspension of submicronic particles of [PO]”. The claim does not define the range for the variables ‘n’ and ‘m’. If  $n=0$ , the ratio ‘ $n/(n+m)$ ’ is also zero.

The term "**sufficiently**" in claim 7 is a relative term which renders the claim indefinite. The term "**sufficiently**" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 17-20 recites the limitation "at least one graft of the polyalkylene glycol type bonded to a glutamate or an aspartate unit" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. The claim 6 from which claims 17-20 depend from recites

limitations limited to polyamino acid formed of aspartic units, glutamic units or both aspartic units and glutamic units and does not recite that ‘polyalkylene glycol’ of claim 17.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6, 16, 21-23, 25 and 26 and are rejected under 35 U.S.C. 102(b) as being anticipated by Huille (US 6,630,171).

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Huille discloses a composition comprising particles of amphipathic linear polyamino acids of aspartates and glutamates (instant PO) having mean particle size less than 200 µm, the polyamino acids bear at least one hydrophobic group R<sup>0</sup> (the instant HG) and at least one active principle (AP). Huille further discloses that particles in aqueous medium forms colloidal suspension spontaneously compatible with the pH of the physiological media and capable of releasing the AP in *vi vivo* under physiological conditions in a sustained and controlled way

(claim 1 of Huille). This reads on the instant claims 1-3 6 and 21. Huille discloses that the number of amino acid units is approximately 500 (approximate Mol. wt. is 75,000 with a molecular weight of glutamic acid being 147) (claim 16). This reads on the instant claim 16 where the molecular weight of the PO is between 2000 and 100,000 g/mol. Huille discloses that the AP can be selected from the group consisting of protein and/or polypeptides, polysaccharides, nucleic acids and mixtures thereof (claim 27) and interferon (claim 31). This reads on instant claims 22 and 23 and the elected instantly species of IFN. Huille discloses that the medical compositions preferably administered orally, nasally, vaginally, ocularly, subcutaneously, intravenously, intramuscular, intraperitoneal and parenterally (columns 9-10, bridging paragraph). This reads on the instant claim 25 and 26.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 3 are rejected under 35 U.S.C. 102(e) as being anticipated by Lambert (US 7030155).

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Lambert discloses an emulsion vehicle for poorly soluble drugs (AP) and discloses a conjugate of vitamin E derivative (tocopherol) comprising a peptide bonded polyglutamate attached to the ring hydroxyl and pegylated phytosterol (column 8, lines 27-32). The tocopherol being the hydrophobic (HG) of the instant application, the polyglutamate is the PO of the instant invention and phytosterol being the AP. Since Lambert discloses the emulsion composition of the instant invention, it is inherent that it possesses the properties of the instant invention such as ‘forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant’.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3, 6, 7, 12-16, 21-23, 25, 26, 28 and 29 are rejected under 35 U.S.C. 102(a) as being anticipated by Chan (US 2006/0099264 A1 is an English language equivalent of WO 03/10403).

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Chan discloses a composition comprising a polyamino acid (claim 15 of Chan) wherein the polyamino acid (PO of instant invention) comprises of aspartic or glutamic amino acid

residues further comprises at least one alpha-tocopherol (instantly claimed HG) (claim 1 of Chan). The composition also comprises at least one active principle (as recited in claim 16 of Chan) and the composition is a colloidal suspension nanoparticles and/or microparticles in an aqueous phase (claim 21 of Chan). This reads on the instant claims 1, 3, 6 and 28. Chan (claim 23) discloses that the injection of composition is capable of forming a deposit at the site of the injection. This reads on the instant claim 2. The general formula of the claim 2 of Chan reads on the formula I of instant claim 7. Chan also discloses that the PO of the invention comprised of L-glutamate homopolymer (claim 6 of Chan) or comprised of L-aspartate homopolymer (claim 7 of Chan) or comprised of L-glutamate/ L-aspartate homopolymer or vice versa (claim 8 of Chan). This reads on the instant claims 12-15. Chan discloses that molar mass of the polyamino acid to be between 2000 and 100,000 g/mol and preferably between 5000 and 40,000 g/mol ([0065] and claim 9). This reads on the instant claim 16. Chan discloses that the composition may be administered via orally, nasally, vaginally, ocularly, subcutaneously, intravenously, intramuscular, intraperitoneal, parenterally or buccal route (claims 19 and 22 of Chan). This reads on the instant claims 25 and 26. Chan discloses that the composition is in the form of a gel, an emulsion, a solution, micelles, microparticles or a powder (claim 20 of Chan). This reads on the instant claim 29.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6, 7, 12-16, 21-26, 28 and 29 rejected under 35 U.S.C. 103(a) as being unpatentable over Chan (US 2006/0099264 A1 is an English language equivalent of WO 03/10403).

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Chan discloses a composition comprising a polyamino acid (claim 15 of Chan) wherein the polyamino acid (PO of instant invention) comprises of aspartic or glutamic amino acid residues further comprises at least one alpha-tocopherol (instantly claimed HG) (claim 1 of Chan). The composition also comprises at least one active principle (as recited in claim 16 of Chan) and the composition is a colloidal suspension nanoparticles and/or microparticles in an

aqueous phase (claim 21 of Chan). This reads on the instant claims 1, 3, 6 and 28. Chan (claim 23) discloses that the injection of composition is capable of forming a deposit at the site of the injection. This reads on the instant claim 2. The general formula of the claim 2 of Chan reads on the formula I of instant claim 7. Chan also discloses that the PO of the invention comprised of L-glutamate homopolymer (claim 6 of Chan) or comprised of L-aspartate homopolymer (claim 7 of Chan) or comprised of L-glutamate/ L-aspartate homopolymer or vice versa (claim 8 of Chan). This reads on the instant claims 12-15. Chan discloses that molar mass of the polyamino acid to be between 2000 and 100,000 g/mol and preferably between 5000 and 40,000 g/mol ([0065] and claim 9). This reads on the instant claim 16. Chan discloses that the composition may be administered via orally, nasally, vaginally, ocularly, subcutaneously, intravenously, intramuscular, intraperitoneal, parenterally or buccal route (claims 19 and 22 of Chan). This reads on the instant claims 25 and 26. Chan discloses that the composition is in the form of a gel, an emulsion, a solution, micelles, microparticles or a powder (claim 20 of Chan). This reads on the instant claim 29.

Chan discloses that greater than 95% association of insulin with the polymer [0139]. However, Chan does not explicitly disclose that the degree of association, i.e., concentration of AP not associated with the polymer is  $\leq 1\%$ , as recited in instant claim 24.

It would have been obvious one of ordinary skill in the art improve the % of non-associated AP with polymer to be  $\leq 1\%$  as Chan has taught the association of AP with the polymer is  $>95\%$ . MPEP section 2144.05 states that “[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the

general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” Additionally, “[T]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” Hence one of ordinary skill in the art would be motivated to optimize the % of association to increase the efficacy of the composition and reduce the cost of the reagent as less non-associated AP molecules are present in the formulation. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined

application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-7, 12-16, 21-23, 28 and 29 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7, 12-16, 21-23, 28 and 29 of copending Application No. 10/580,037. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending Application No. 10/580,037 is drawn to interferon a species of the genus active principle of instant invention. According to MPEP section 2131.02 [R-6], “A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus.” The

species in that case will anticipate the genus. Hence the claims of the copending Application No. 10/580,037 anticipates the instant invention.

2. Claims 1-7, 12-16, 21-23, 28 and 29 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 12-15 and 20-26 of copending Application No. 10/580,035. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending Application No.

10/580,035 is drawn to interleukin a species of the genus active principle of instant invention.

According to MPEP section 2131.02 [R-6], “A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus.” The species in that case will anticipate the genus. Hence the claims of the copending Application No. 10/580,037 anticipates the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-3, 6, 7, 12-16, 21-26, 28 and 29 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 15-22 of U.S. Patent No. 7,683,024.

In the instant application applicants claim a liquid pharmaceutical formulation for the prolonged release of active principle (AP) comprising an aqueous colloidal suspension of submicronic particles of water-soluble biodegradable polymer (PO) carrying hydrophobic groups (HG) and at least one AP and exhibits the property of forming gelled deposit *in vivo* when injected parenterally and formulation is at physiologic pH, temperature and in the presence of physiological electrolyte and at least one surfactant.

Chan discloses a composition comprising a polyamino acid (claim 15 of Chan) wherein the polyamino acid (PO of instant invention) comprises of aspartic or glutamic amino acid residues further comprises at least one alpha-tocopherol (instantly claimed HG) (claim 1 of Chan). The composition also comprises at least one active principle (as recited in claim 16 of Chan) and the composition is a colloidal suspension nanoparticles and/or microparticles in an aqueous phase (claim 20 of Chan). This reads on the instant claims 1, 3, 6 and 28. Chan (claim 22) discloses that the injection of composition is capable of forming a deposit at the site of the injection. This reads on the instant claim 2. The general formula of the claim 2 of Chan reads on the formula I of instant claim 7. Chan also discloses that the PO of the invention comprised of L-glutamate homopolymer (claim 6 of Chan) or comprised of L-aspartate homopolymer (claim 7 of Chan) or comprised of L-glutamate/ L-aspartate homopolymer or vice versa (claim 8 of Chan). This reads on the instant claims 12-15. Chan discloses that molar mass of the polyamino acid to be between 2000 and 100,000 g/mol and preferably between 5000 and 40,000 g/mol ([0065] and claim 9). This reads on the instant claim 16. Chan discloses that the composition may be administered via orally, nasally, vaginally, ocularly, subcutaneously, intravenously, intramuscular, intraperitoneal, parenterally or buccal route (claims 21 and 23 of Chan). This reads

on the instant claims 25 and 26. Chan discloses that the composition is in the form of a gel, an emulsion, a solution, micelles, microparticles or a powder (claim 20 of Chan). This reads on the instant claim 29.

Chan discloses that greater than 95% association of insulin with the polymer [0139]. However, Chan does not explicitly disclose that the degree of association, i.e., concentration of AP not associated with the polymer is  $\leq 1\%$ , as recited in instant claim 24.

It would have been obvious one of ordinary skill in the art improve the % of non-associated AP with polymer to be  $\leq 1\%$  as Chan has taught the association of AP with the polymer is  $>95\%$ . MPEP section 2144.05 states that “[G]enerally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” Additionally, “[T]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.” Hence one of ordinary skill in the art would be motivated to optimize the % of association to increase the efficacy of the composition and reduce the cost of the reagent as less non-associated AP molecules are present in the formulation. A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within

the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned applications and/or US Patent, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SATYANARAYANA R. GUDIBANDE/  
Examiner, Art Unit 1654

/Andrew D Kosar/  
Primary Examiner, Art Unit 1654